SUMMARY OF JANUARY 2000 PHS ADVISORY COMMITTEE MEETING ON BLOOD SAFETY AND AVAILABILITY

Committee Update

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PHS Advisory Committee on Blood Safety and Availability, PHS, HHS

65th Meeting
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Holiday Inn, Silver Spring
8777 Georgia Avenue
Silver Spring, MD

DATE: February 7, 2000

TO: Interested Parties

FROM: Stephen D. Nightingale, M. D., Executive Secretary

Advisory Committee on Blood Safety and Availability

SUBJECT: Summary of January 26th and 27th, 2000 Meeting

The Advisory Committee on Blood Safety and Availability met for the tenth time on the above mentioned dates at the Hyatt Regency Capitol Hill Hotel, 400 New Jersey Ave., N. W., Washington, D. C. 20001 to consider Errors and Accidents in Blood Administration: What Can Be Done to Reduce Their Occurrence? Because of inclement weather, the start of the January 26th meeting was delayed until 1:00 PM. Voting members present at the meeting were Dr. Caplan, the Chairman; Mr. Allen; Drs. AuBuchon, Busch, Davey, Gilcher, Gomperts, Guerra, Hoots, and Kuhn; Mss. Lipton and Pahuja; Drs. Penner, Piliavin, and Secundy; Mr. Walsh; and Dr. Winkelstein. Dr. Haas was unable to attend. Ex-officio members present were Drs. Chamberland, Epstein, McCurdy, and Snyder. LT COL Fabrizio Sarecini represented the Department of Defense on behalf of COL Fitzpatrick; Dr. Goosby was unable to attend. Also present were Dr. Nightingale, CAPT McMurtry, the Deputy Executive Secretary, and approximately 30 members of the public. At the time the meeting began, Drs. Busch, Caplan, Penner, and Piliavin, Epstein, and Snyder were still in transit; Dr. AuBuchon chaired the meeting until Dr. Caplan's arrival.

I AN OVERVIEW OF APPROACHES TO THE MANAGEMENT OF HUMAN ERROR

Dr. David Satcher, the Assistant Secretary for Health and Surgeon General, began his remarks by welcoming Dr. Davey, Mss. Lipton and Pahuja, and Dr. Winkelstein to the Committee, and thanking Drs. Gilcher and Hoots, and Mr. Walsh, for agreeing to serve another term. He then charged the Committee to consider how the shared concerns of many groups and individuals on the subject of errors and accidents in transfusion medicine could be translated into effective action. He specifically requested consideration of the relative merits of mandatory and voluntary reporting systems and automated patient identification systems, but he also encouraged all participants and guests to consider other initiatives as well.

Dr. Kenneth Shine, the President of the Institute of Medicine, then discussed the Institute's recent report "To Err Is Human: Building a Safer Health Care System." He began by emphasizing the focus of the report on system rather than individual performance, and its intent to elicit constructive response rather than finger pointing. He noted society's need to close the considerable gap between the average and the best medical care, and he stated that managed care could not be blamed for this gap. He pointed out that tolerance for error is much lower in other industries than in medicine, and he encouraged the profession to strive for these higher standards.

Dr. Shine then summarized the recommendations of the Institute of Medicine report. These include mandatory, state-based, standardized, publicly accessible, organization-level reporting of serious injuries or deaths; and voluntary, confidential reporting of minor injuries or near misses. Dr. Shine stressed the need for ongoing collection of data about errors and accidents, and the need to develop a culture of safety within healthcare organizations. A reflection of this culture, he said, would be the global adoption of computerized order/prescription entry and information management. Dr. Shine noted the broad support for the Institute of Medicine's report, and he concluded by noting with pleasure that the existence of the Advisory Committee on Blood Safety and Availability was a

consequence of a previous Institute of Medicine report.

In response to questions from the Committee, Dr. Shine acknowledged the progress towards error containment that had already been made in blood banking and anesthesia, and he expressed hope that this progress could be replicated in other areas in medicine. He also acknowledged concern of providers about the potential impact of litigation on both safety and availability of medical care. In response to Dr. Gilcher, Dr. Shine admitted that his definition of error - the failure of a planned action to be completed as intended (an error of execution), or the use of a wrong plan to achieve an aim (an error of planning) - and adverse event - an injury caused by medical management rather than by the underlying disease or condition of the patient - permits any undesired or unexpected medical outcome to be construed as an error or adverse event, and that is not always appropriate.

Mr. Robert Francis, the Immediate Past Vice Chairman of the National Transportation Safety Board, urged the audience not to use fear of litigation as an excuse not to act, because failure to adopt available error-reduction strategies might create as much liability as adoption of these strategies. He repeatedly criticized a recent New York Times article that quoted reservations about the Institute of Medicine report. Mr. Francis emphatically made the point that "picking pieces of aircraft out of South Dakota" was not the optimal approach to error management in aviation. He instead recommended confidential, voluntary systems such as the one used by American Airlines to identify patterns of behavior before they cause harm. He alluded to the tradeoffs in local authority that the aviation industry, its unions, and the Federal Aviation Administration had to accept in order to achieve the improved passenger safety this system has provided. Mr. Francis urged the health care industry to adopt a comparable error management strategy before it is forced to do so by Congress. He cited flawed legislation requiring collision avoidance systems on commercial passenger but not freight aircraft to buttress this last argument.

In response to questions from the Committee, Mr. Francis noted that voluntary reporting does not automatically confer immunity to the reporter. At the same time, any violation of the trust implicit in such a system will severely impair it. Mr. Francis also noted that on-line flight recording devices had made voluntary reporting more a matter of determining why, rather than whether, an error had occurred. Mr. Allen expressed concern that error and accident tracking and reporting systems might be more responsive to providers rather than consumers of health care, particularly in regard to access to information about an error or accident and its final disposition, and specifically in cases where the provider and consumer differed about the importance of the event.

Dr. Charles Bosk, Professor of Sociology at the University of Pennsylvania, provided a historical perspective on the medical profession's approach to error management, which began well before the Institute of Medicine report . He expressed concern that present discussions may assume, incorrectly, that in any clinical situation there is always one good choice. Dr. Bosk reviewed

1. "Mistakes at Work" by Everett Hughes (I 95 1), which described team structures in medicine as vehicles both to improve care and to diffuse responsibility;
2. "Doctoring Together" by Elliott Friedson (1976), which described a lack of social control of substandard performance within a medical institution;
3. "Becoming Psychiatrists" by Donald Light (1979), which described peer review of an adverse outcome as a reintegration ritual; and
4. "Forgive and Remember" by Dr. Bosk (1981), which proposed a classification of medical errors into

    1. blameless (technical, so long as they occurred only once, and judgmental, which was implicit in the high social standing of the chief of service who made or agreed with the call); and

B. blameworthy (violation of behavior codes held by society as a whole, such as not getting informed consent, or violation of behavior codes held by the immediate group, such as what kind of suture to use on a particular wound).

Dr. Bosk emphasized that the latter were taken as seriously by the profession as the former. He observed that blameless errors elicited instruction or discussion, while blameworthy errors elicited public scapegoating. He noted "the sad sociological truth" that a periodic public exemplary punishment appeared necessary to maintain awareness of group norms.

Dr. Bosk admonished the Committee not to assume that detection of error in medicine was

simply a form of bird-watching, and that all one has to do is look through the binoculars, identify the species, and put it on a chart. He emphasized that the definition of error is still contestable - particularly if one person approaches the issue prospectively, and another approaches it retrospectively. Dr. Bosk warned the Committee that the paucity of good models for teamwork in medicine, the cost of error management, current reimbursement practices, and the peculiar commitment of American medicine to aggressive interventional practices were all impediments to achievement of the ultimate goal of error management, the reduction of human suffering.

In response to questions from the Committee, Dr. Bosk concurred that there is a very substantial gap between the very close regulation of drugs, devices, and biologics by FDA and the minimal regulation of medical procedures. Dr. Bosk suggested that appropriate attention to informed consent might resolve this situation, and also clarify the distinction raised previously by Dr. Gilcher between an appropriate but unsuccessful therapeutic intervention and an error in medical practice.

Mr. Allen asked Dr. Bosk to comment on physician communication of errors and accidents to patients. Dr. Bosk responded that, in his studies, not only did physicians not communicate their own errors to patients, but they did not communicate other physicians' errors to patients. Dr. Bosk then noted that more recent experience indicates that better communication of such matters by physicians to patients is in the interest of physicians as well as patients. Mr. Allen asked if this was not an argument for more mandatory disclosure of errors and accidents. Dr. Bosk demurred, citing a recent report that in the first eighteen months after Pennsylvania had mandated the reporting of 13 categories of adverse event, the 35 busiest hospitals in metropolitan Philadelphia had collectively reported only one such event, whereas over 10,000 such reports would have been expected.

Dr. Ronald Westrum, Professor of Sociology at Eastern Michigan University, began his discussion about organizational response to errors and accidents by reviewing a schema developed by Dr. James Reason. Reason has proposed that accidents characteristically result from the interaction of an active error by a system operator and a hidden unsafe condition - for example, a piano in front of a fire escape. Dr. Westrum has classified organizational responses to the possibility of such hidden conditions, or "latent pathogens", in three ways: denial, passive acceptance, and active response. These responses define organizations that are, respectively,

1. Pathologic. The defining characteristic of a pathologic culture is the protection, ennoblement, and celebration of powerful people. Information is hoarded, messengers are

shot, responsibilities are avoided, failure is punished, and new ideas are crushed.

2. Bureaucratic. The defining characteristic of a bureaucratic culture is conformance to rules; the outcome is less important than the process. Information may be neglected, responsibility is narrow, the organization is just and merciful, and new ideas create problems, although they may eventually be adopted.
3. Generative. The defining characteristic of a generative culture is focus on outcomes. Information is cultivated, messengers are trained, responsibilities are shared, failure prompts systemic inquiry, and new ideas are welcomed.

Generative cultures are cultures of conscious inquiry. Awareness and learning are attributes of the organization itself, and this promotes the identification and correction of latent pathogens before they cause errors and accidents. Dr. Westrum cited anesthesia as a field within medicine where latent pathogens, notably at the interface between human operators and machinery, have been identified and corrected. This has been accomplished by facilitating voluntary communication among members of the field, using techniques based on "crew resource management" as pioneered in the aviation industry by Dr. Robert Helmreich and others.

Dr. Westrum acknowledged the difficulty of achieving cultural change in organizations. In a pathological culture, for example, change permits members of the culture, particularly powerful ones, to behave badly, even up scores, shift power, remove resources from those they dislike, and so on. Nevertheless, he concluded that in order to fix medical problems, it may be necessary to change organizational cultures that predispose to these problems.

II MANDATORY AND VOLUNTARY REPORTING OF TRANSFUSION ERROR

After a break, Dr. Jean Linden, Director of Blood and Tissue Resources, New York State Department of Health, discussed the experience of her agency with mandatory reporting of errors and accidents in transfusion medicine. She described four hidden systemic faults that were identified by analysis of these mandatory reports and subsequently corrected. The first involved patient misidentification that was associated with sequential assignment of medical record numbers; the second involved misreading a laboratory report that was poorly transmitted by a fax machine. A third involved inadequate training of all potential users of a complex operating room device; the fourth involved part-time users of a facility who did not adhere to the facilities standard operating procedures.

Dr. Linden acknowledged that New York's mandatory reporting system can be considered a passive information gathering system, but she pointed out that completeness of reporting is validated during biennial facility surveys. She noted that the confidentiality of New York's reporting system is explicitly protected by law, and that it is non-punitive. She also noted that New York collects supplemental data, such as volume of procedures, from its regulated facilities, so that it can estimate incidence as well as crude number of errors and accidents. Information is collected in narrative form, reviewed by Dr. Linden's office (which may request additional information), and then encoded. Dr. Linden's office does collaborate with New York's Patient Occurrence Reporting and Tracking System, the Joint Commission on Accreditation of Healthcare Organizations, and the Food and Drug Administration.

Dr. Linden's data suggest that, over the past decade, the incidence of ABO-incompatible blood transfusions has been about 1 in 37,000, that the incidence of ABO-inconsistent (but not necessarily incompatible, e. g., O blood into an A recipient) blood transfusions has been about 1 in 13,000, and that the incidence of deaths attributable to incompatible blood transfusions has been about 1 in 2,000,000. (Dr. Linden noted that not all recipients of an incompatible transfusion die, and that not all who die after an incompatible transfusion die because of the transfusion.). As a point of reference, the current risk of acquiring any one of the many transfusion- transmissible diseases from a blood transfusion is about 1 in 34,000.

Dr. Linden noted that her detected incidences of transfusion errors and accidents have been relatively stable over the past decade. This could be due to better error detection, which would mask an overall decrease in error incidence. Over half of the transfusion errors identified by Dr. Linden have been due to misidentification of the patient at the bedside; 12% have been due to misidentification of the donor, and 30% to testing or clerical errors in the blood bank, and 15% to multiple errors.

Ms. Sue Fenza Reardon of the Carle Clinic Laboratories then described current practices within transfusion services to manage errors. She identified the American Association of Blood Banks, the Foundation for the Accreditation of Hematopoietic Cell Therapy, the Food and Drug Administration, the Joint Commission on Accreditation of Healthcare Organizations, the College of American Pathologists, the Health Care Financing Administration, and the International Standards Organization as agencies that impose requirements on transfusion service operations; all but the last has reporting requirements as well.

Ms. Reardon commented that automation has the potential to reduce human error, but only if the automation is validated and continuously monitored. She noted that the previous practice of error management to "blame and train" was being superceded by more attention to process review, particularly when a standard operating procedure is changed. She also observed that production processes tend to mutate over time. A major challenge to error management is the determination of when isolated events become a trend. Ms. Reardon discussed the use of Pareto diagrams and other analytic tools for this purpose, and she noted that many of these had been incorporated into computerized error analysis systems.

Ms. Sharon O'Callaghan of the Food and Drug Administration (FDA) then discussed FDA's mandatory reporting requirements for blood establishments and transfusion services. At 21 CFR 600.14, FDA requires that licensed blood establishments report errors or accidents in the manufacture of products that may affect the safety, purity, or potency of any product. Manufacture includes the collection, preparation, processing, compatibility testing, or other procedures of any blood product that meets the definition of a drug, and includes manipulation, sampling, testing, or control procedures applied to the final product. Manufacturing does not, however, include the actual administration of the product. In 1991, FDA issued a letter requesting unlicenced blood banks or transfusion services to voluntarily meet these reporting requirements. In 1997, FDA issued a proposed rule that would make reporting by these unlicenced entities mandatory. The proposed rule defines an error or accident to be

1. a deviation from current Good Manufacturing Practices, applicable standards, or established specifications; or

2. an unexpected or unforeseen event that may affect the safety, purity, or potency of a product, or otherwise cause a product to be in violation of the Food, Drug, and Cosmetic Act or Public Health Service regulations, if that product has been determined to meet all release criteria and to be suitable for distribution, whether or not actual distribution has occurred.

Ms. O'Callaghan projected that 25,000 such reports will be received in the current fiscal year. She noted that in fiscal 1999 there had been 13,280 reports from licensed blood banks, but only 127 reports from approximately 2,800 unlicenced blood banks, and only 30 reports from approximately 6,000 unlicenced transfusion services. She also noted that 78% of the reports received in fiscal 1999 concerned information about blood donors that was received after a donation was made (for example, the donor had traveled to an area endemic for malaria). Detailed quarterly summaries of these reports are posted on the FDA web site.

Ms. O'Callaghan then discussed 21 CFR 606.170(b), which requires that FDA be notified as soon as possible after a complication of blood collection or transfusion is confirmed to be fatal. This requirement applies to unlicenced as well as licensed facilities. There were 15 confirmed hemolytic transfusion reactions in 1996, 14 in 1997, 11 in 1998, and 7 in 1999. Four of these 7 fatalities were attributed to errors in the blood bank, and three were attributed to errors at the point of administration. Other fatal complications of blood transfusion reported in 1999 were bacterial contamination (12), transfusion-related lung injury (10), graft vs host disease (3), transfusion-transmitted disease (2), anaphylaxis (2), and hypovolemia (3).

In the discussion that followed, Dr. Epstein commented that the separation of reporting systems for manufacturing events and for administration events reflects FDA's statutory focus on manufactured products and claims about them, whereas administration issues are medical use issues not historically within FDA's domain.

Dr. James Battles, Professor of Medical Education at the University of Texas Southwestern Medical Center, then discussed the construction of the Medical Event Reporting System for Transfusion Medicine (MERS-TM). The goal of this research, which has been funded by the National Heart, Lung, and Blood Institute, has been to develop a national standard methodology for transfusion event reporting. The immediate benefit of implementing this system is improved knowledge about transfusion practices; the ultimate benefit is improved transfusion safety.

Dr. Battles noted that there was little precedent for such a system within medicine, so he and his colleagues began by using a Delphi technique, and initiating this process at discussion of the Aviation Safety Reporting System. Participants in these discussions included representatives from FDA and industry. The group recommended that the system should

1. be confidential and non-punitive;
2. be integrated into quality assurance systems currently in place and required for accreditation or by regulation;
3. capture information about near misses as well as direct hits;
4. contain a classification schema for events it detects;
5. identify root causes of these events; and
6. be a useful management tool at the level of the blood centers and hospitals that use it.

Dr. Battles stressed the importance of

1. benign event and near miss data as a resource for identifying successful error-prevention strategies;
2. the benefit of basing reporting systems, particularly for near-misses, outside the regulatory framework;
3. the importance of a low threshold for detection of events; and
4. the need for automated analyses in a system that actively seeks such a large amount of raw data.

Dr. Battles noted that the MERS-TM algorithm, which uses a tree structure to identify

antecedent, and possibly causal, events, and assumes more than one root cause will be identified, has evolved from a system developed at Eindhoven University in the Netherlands to manage errors and accidents in the petrochemical industry.

Dr. Harold Kaplan of Columbia University then discussed recent experience with the MERS-TM system. He described a near-miss labeling error that was identified, analyzed, and corrected. In this case, labels to be placed on consecutive units of blood were printed on the same paper tape. It was not clear to the phlebotomist where on the tape the label for one unit ended and the label for the next unit began. The phlebotomist tore the tape at the wrong point, and so the second unit was mislabeled, and this mislabeling was captured by the MERS-TM system. The error was corrected by more clearly identifying the point on the paper tape where one label ended and another began with a fat black line.

Dr. Kaplan used this example to reiterate the need for unrestricted data input into an effective error identification, analysis, and management system. He also reiterated the importance of shifting from a "blame and train" error management system to one that actively recruited input to a confidential, non-punitive system. In his initial experience, this resulted in a ten-fold increase in error reporting. This included not only reports of near-misses, but also reports of shop-level corrective actions that had not been previously recorded.

Dr. Kaplan discussed the possibility that the MERS-TM system might identify some system operating characteristics that do not merit corrective action. He noted that merely changing a single standard operating procedure in a complex system could conceivably be riskier than leaving the standard operating procedure unchanged. To account for this possibility, the MERS-TM system incorporates an action-decision tree that weighs frequency, severity, probability of recurrence, and delectability to recommend one of several options, which may range from continued data collection through a more focused audit to a specific corrective action.

Dr. Kaplan described a focused audit in an obstetric service that found several instances of multiple patients using the same identification/insurance card. He then presented data on the similarities in root causes of error that the MERS-TM algorithm had identified in transfusion medicine and the root causes of error that the relative of this system, the Eindhoven classification scheme, had identified in the petrochemical industry. Dr. Kaplan concluded his talk by describing several expected consequences of implementing an effective event reporting system:

1. detection sensitivity increases over time;
2. system-critical failure points and common factors in system failures become apparent;
3. continuous monitoring of system performance is established;
4. root causes are corrected before overt failures occur; and
5. a passive approach to safety within a culture becomes an active approach.

At the conclusion of Dr. Kaplan's presentation, the meeting was recessed at 7:26 PM.

III. OLD BUSINESS

The meeting resumed at 8:11 AM on January 27th. Dr. Arthur Caplan opened the session by suggesting that lessons learned about managing error in transfusion medicine might be applicable to medicine as a whole.

Dr. Miriam Alter of the Centers for Disease Control then presented an update on targeted and general notification programs for hepatitis C lookback. She described the interim results of a survey initiated in mid-November 1999 of 200 blood collection establishments and 5,468

hospital transfusion services. These interim results suggest that he number of direct notifications triggered by this program may be in the neighborhood of 40,000 individuals, somewhat less than one-third of previous estimates.

Dr. Alter stated that about 80% of the responding blood establishments reported that they had completed at least 90% of multiantigen test-triggered notification of consignees. Responding transfusion services reported they had completed the notification process for 80% of recipients of components from multiantigen-tested donors. Single antigen test-triggered notification, which has a later deadline, has not progressed as far; only 15% of blood establishments reported that they had completed all consignee notifications.

These preliminary results suggest that, for multiantige test-triggered notification,

1. about 70% of the total population targeted for direct notification has died;

2. about 23% of the total population targeted for direct notification has been contacted;

3. about 2% of the total population targeted for direct notification has been found to be

infected with hepatitis C virus; and

4. about half of these - very roughly, about 400 individuals, or 1% of the total population targeted for direct notification - were previously unaware of their infection.

In the discussion that followed, Dr. Davey estimated that the American Red Cross has spent about $10 million on its component of the notification effort.

CAPT Mary Gustafson of FDA then discussed of implementation of the November 1999 amendment to the Blood Action Plan that addressed the adequacy of the blood supply. This amendment has been discussed at the August 1999 Advisory Committee meeting. Dr. Gustafson summarized the Department's responses to each of the five components of this amendment as follows:

1. Monitoring the blood supply: The National Heart, Lung, and Blood Institute (NBLBI) contracted in December 1999 with the National Blood Data Resource Center to conduct monthly surveys of 30 blood establishments. The first data is to be delivered in mid-February 2000.
2. Encourage more donations by eligible donors: NHLBI will sponsor a workshop in late February 2000 on strategies to increase blood donations. FDA will publish a Guidance on donor incentives by the end of June 2000,
3. Improve donor relations: FDA and NHLBI will convene a donor recruitment workshop by the end of August 2000. Also, FDA intends to publish a Guidance on computer-based donor questionnaires by the end of September 2000. FDA plans to address the issue of shortening or simplifying the current donor questionnaire by the end of December 2000.
4. Remove restrictions to safe donations: FDA will issue a Guidance on use of blood obtained from therapeutic phlebotomy of individuals with hemochromatosis by the end of May 2000. FDA has already approved two applications for exceptions to its current regulations on this issue. Also, FDA plans workshops to examine other actions it might take. However, since many of them may be related to the implementation of nucleic acid testing (NAT) for viral pathogens, consideration of these issues may not be possible until 2001, when evaluation of NAT is expected to have been completed.
5. Address economic issues facing the blood industry: The Advisory Committee addressed the issue of reimbursement for-outpatient use of blood and blood products at its August 1999 meeting, and will address the issue of reimbursement for inpatient use of these products, and other related matters, at its April 2000 meeting.

After CAPT Gustafson's comments, there was a brief discussion about the capacity of the blood supply to respond to a natural disaster or an act of bioterrotism. Drs. Davey and Epstein indicated that both the private and public sectors were addressing these issues.

Dr. Francine Decary, Executive Director of Hema-Quebec, then discussed the response of her agency to the challenges posed by variant Creutzfeldt-Jakob disease (vCJD) deferral policies. Dr. Decary began by noting that Canadian blood policies were guided by the recommendations of the 1997 Commission of Inquiry on the Blood System in Canada (the Krever Report), the second of which is that

> Preventive action should be taken when there is evidence that a potentially disease-causing agent is or may be blood borne, even when there is no evidence that recipients have been affected. If harm can occur, it should be assumed that it will occur. If there are no measures that will entirely prevent the harm, measures that may only partially prevent transmission should be taken.

Dr. Decary noted that it was well recognized that the shortage of blood itself is a definite risk, and that a five percent acute reduction in the blood supply was as much as her agency felt could be handled safely. In January 1999, Hema-Quebec performed a survey to estimate the impact of various donor deferral strategies on the current donor pool. This survey projected that a deferral of donors who had spent one month or more in the United Kingdom since 1980 would reduce the current donor pool by 3% and eliminate 87% of risk based on the assumption that every day a donor spent in the United Kingdom since 1980 contributed equally to the total risk.

To compensate for the anticipated shortfall of approximately 9,750 donors (and 15,600 donations), Hema-Quebec moved to assure that its collection facilities were as prepared as possible to service donors when they arrived, and increased the frequency of its blood drives. They also invested approximately $800,000 (Canadian) in publicity, which with in-kind contributions and support from the Blood Volunteers Association resulted in about $2,500,000(Canadian) in net exposure.

Hema-Quebec implemented its vCJD donor deferral policies on September 30, 1999. In the three months that followed, an average of 0.7% of donors were deferred because of this policy. Since a 3% donor deferral rate was anticipated, it appears likely that many affected donors self-deferred. At the same time, the number of Hema-Quebec's donors in the last quarter of the year increased from 72,436 in 1998 to 74,689 in 1999.

Dr. Decary summarized her remarks by noting that, to compensate for the anticipated donor shortfall, Hema-Quebec increased the number of its mobile collections, and went to places where it used to go on a regular basis, but not often, to get regular donors. Hema-Quebec also increased its publicity. Dr. Decary concluded by noting that the publicity strategy was focused on children who had actually received blood in the past two years, because their marketing research had

confirmed that people give blood for a recipient, and not for an organization, and the focus based on this research had proven quite effective.

Dr. Graham Sher, Vice President for Medical Affairs of Canadian Blood Services (CBS), presented a complementary summary of his experience. CBS performed a survey similar to the one conducted by Hema-Quebec. This survey projected that a deferral based on six or more cumulative months of residence in the United Kingdom would result in a 2.5% donor deferral rate among CBS donors. The observed deferral rate after the VCJD policy was implemented on September 30, 1999 was 1.4% in October, 0.7% in November, and 0.8% in December; for the first two weeks in January 2000 it is 0.4%. Dr. Sher suggested that this difference between predicted and observed deferral rates could, as

Dr. Decary had proposed, reflect self-deferral by donors who had been made aware of the new policy.

Like Hema-Quebec, CBS increased its collection efforts, and launched a multi-media donor recruitment advertising campaign based on the theme "If You Knew ... Would You?" that cost roughly $3,500,000 (Canadian). This campaign included a direct mailing to 1.3 million previous donors, which itself cost about $1,000,000 (Canadian). Response to this campaign has included an increase in new and returning donors, particularly young donors, and an increase in donations compared to the same time period in the two previous years.

In the discussion that followed, Dr. Busch noted that he had proposed a similar campaign in his own bloodcenter, but that funding was not available for it. Mr. James McPherson of America's Blood Centers (ABC) noted that the two preceding years had been difficult ones for Canada's blood operators, and that might complicate interpretation of the results presented.

When discussion of these presentations had concluded, Dr. Caplan proposed the following motion:

> **The Committee directs its staff to create on the Committee's web site a list of key recommendations that the Committee has made, in a format that would permit the public to see what progress has been made in implementing each of these recommendations.**

Dr. Penner seconded the motion. The motion was unanimously approved.

IV. ADDITIONAL MEASURES TO REDUCE THE INCIDENCE OF TRANSFUSION ERRORS AND ACCIDENTS

After a break, Dr. S. Gerald Sandler, Professor of Medicine at Georgetown University, discussed his own experience with a system to reduce misidentification of blood and blood recipients. Dr. Sandler stated for the record that he had in the past received honoraria from the manufacturer for speaking about his experience, but that he had no financial interest in the manufacturer or the product. Dr. Sandler stated he had used the system, known as the I-TRAK Plus, in over 500 transfusions to date. The system uses bar coding to insure information integrity and a portable data terminal and printer to make and read labels that track blood products from their withdrawal from a donor through testing and storage to their infusion into a recipient; Dr. Sandler's presentation illustrated these steps.

In the discussion that followed, Mr. McPherson recalled that the Committee for Commonality and Blood Banking Automation had proposed the development of such a system over two decades ago, and perhaps the time had come to consider such a specification in Good Manufacturing Practices for blood. Dr. McCurdy recalled that a similar system had been in use some time ago but had been discontinued because of cost. LT COL Sarecini suggested that systems such as Dr. Sandler described would be more expensive per unit labeled in smaller than in larger institutions because capital equipment costs would have to be distributed among fewer units processed.

Dr. AuBuchon then demonstrated a blood lock system that has been in use in his institution for over 8 years and in over 80,000 transfusions. A small plastic lock prevents use of a unit of blood until it is released. Release of the lock requires reading a code on the patient's wrist band and entering that code into the plastic lock. This prevents administration of the unit to an individual who is not wearing a wrist band with the proper code.

Dr. AuBuchon also commented favorably on the I-TRAX system, particularly its ability to document each step in the transfusion chain. He said, however, that there were some circumstances (such as operating rooms) where the blood lock might be preferable, and he felt that use of one system in one setting need not preclude the use of a different system in a different setting.

PUBLIC COMMENT

Ms. Kay Gregory of the American Association of Blood Banks (AABB) summarized her written statement that was provided to Committee members. She noted that the AABB standard 7.000 requires that

> A blood bank or transfusion service shall have a process to ensure the capture,
>
> assessment, investigation, and monitoring of events that deviate from accepted policies, processes, or procedures or that fail to meet the requirements of the blood bank or transfusion service, these Standards, or applicable laws and regulations.

The 20th edition of the AABB Standards will include an entire section specifically relating to incidents, errors, accidents, nonconforming products and services, and complications.

Ms. Gregory alluded to the experience of the BaCON (bacterial contamination) study to express reservations whether, in the current reimbursement climate, it was reasonable to expect compliance of transfusion services with any voluntary measure unless funding was provided for it. Ms. Gregory also expressed concern that a system for reporting near-misses have adequate capacity to process and analyze the data it might receive, and she emphasized the need for any reporting system to be user friendly and to provide meaningful data. Ms. Gregory expressed support for the National Blood Data Resource Center's involvement in a voluntary reporting system, and expressed interest in utilizing something like the MERS-TM system.

Mr. James McPherson of America's Blood Centers (ABC) supported the extension of FDA mandatory reporting requirements to all blood facilities. He made the Committee aware of an ABC program called CITINGS. This is a system for the anonymous reporting or regulatory actions and the response of the reporting entity to those actions. Summary statistics are reported quarterly. In his written statement, Mr. McPherson supported the MERS-TM system, saying it

should be implemented and will yield valuable data. ABC recommended that

1. FDA extend the current error and accident reporting requirement to apply to all blood establishments and hospital transfusion services, rather than only registered blood establishments.

2. HCFA adopt a requirement that hospitals report to FDA all adverse transfusion-related outcomes related to errors and accidents. Further, HCFA should require that hospitals actively use data to develop intervention strategies related to the root causes of adverse transfusion-related incidents.

3. HCFA determine compliance with these reporting and follow up requirements through active inspection, either state inspections or those conducted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). If this is not feasible, FDA should inspect transfusion services to assure compliance with FDA requirements.
4. FDA should publish at least semiannual analyses both of the root causes of common or

potentially new trends in errors and accidents, and examples of corrective actions.

5. A non-punitive, voluntary reporting system as suggested by Dr. Kaplan (MERS-TM or an equivalent system) be instituted to capture near misses or other mistakes that could have contributed to an error or accident with analyses similar to that describe in 4 above. The intent of such a voluntary system would be to capture data that would not otherwise be reported by FDA mandate. This system could be instituted under a grant from the National Institutes of Health to a private sector organization and, if successful, might be continued through self-funding (e. g., subscriber fees). Who would report and what would be reported could be left up to the person making the report (based on some type of established guidelines, such as those Dr. Kaplan developed with industry and government input). Also, reports could be accepted by anyone including employees, management, donors, hospital customers, etc.

Ms. Marilyn Sue Bogner, the author of Human Error in Medicine (Erlbaum, 1993), which had been provided to each of the Committee members prior to the meeting, then briefly reminded the Committee to consider not only the forces acting within an institution, but also the forces acting on an institution (e. g., regulatory climate and reimbursement policies) when constructing recommendations on how to decrease errors and accidents in that institution.

Mr. Corey Dubin of the Committee of Ten Thousand began his remarks by concurring with earlier comments that stakeholders would benefit more by addressing the issue of errors and accidents themselves than by waiting for Congress to address it for them. He encouraged those proposing strategies to reduce errors and accidents to incorporate consumers as active participants in these strategies, rather than isolating consumers as merely potential litigants.

Mr. Dubin observed that consumers of blood and blood products should be receptive to this strategy because they had achieved more through collaboration in the development of public policy than they had through confrontation in the judicial system. To illustrate this point, he alluded to the public trust that is emerging for Canada's evolving blood system as a factor that contributed to the successful Canadian donor recruitment campaign following implementation of vCJD donor deferral policies. He suggested that one outcome of current policy discussions might be a no-fault compensation program for unintentional blood injury. He proposed this as an example of how legitimate liability concerns might be addressed.

Mr. Dubin emphasized that a culture of safety would require an understanding that people make mistakes, although not an acceptance of gross negligence. He endorsed the general concepts behind the systems described by Drs. Linden and Kaplan, and he pointed out that implementation of these systems might require funds not currently available.

Mr. Dubin then returned to the core of his message, which was that a precondition for establishing a culture of safety is trust. Mr. Dubin emphasized the importance of reporting near misses as well as direct hits, so that situations could be corrected before harm resulted. He noted the difficulty of deciding what information reports should be mandatory and what could be voluntary. He pointed out, as had others before him, that compliance with mandatory reporting of errors and near misses is, ultimately, a voluntary act.

Ms. Jan Hamilton of the Hemophila Federation of America expressed optimism about the error correction systems discussed at the meeting. She urged that all blood establishments and transfusion services adopt MERS-TM or a comparable system so that all errors and accidents would be reported, subjected to a root cause analysis, and corrected. She felt that if this

required that reporting of all errors and accidents be mandatory, so be it. She particularly urged that all blood establishments and transfusion services be licensed and held to a uniform set of standards.

Mr. Richard Crato of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) noted the congruence of his organization's activities, particularly in respect to responses to sentinel events, with the proposals before the Committee. He noted that JCAHO's concern with errors and accidents extended to the entire spectrum of health care. He emphasized the need for thorough analysis of reported events, for Federal protection of the confidentiality of error and accident reports, and for sharing of de-identified reports and analyses with other agencies and institutions working to improve health care. Mr. Crato expressed hope that lessons being learned from analyses of sentinel events could soon be applied to a proactive risk reduction model for all of health care, and that principles of risk reduction would soon be incorporated into the educational curriculums of all health care professionals.

Mr. Stephen Northrup of the Medical Device Manufacturers Association requested the Committee consider recommending that review of medical devices now conducted by the Center for Biologics Evaluation and Research (CBER) at FDA be transferred to the Center for Devices and Radiologic Health (CDRH). Mr. Northrup cited data indicating substantially shorter review cycles at CDRH in support of his request.

Ms. Marian Sullivan of the National Blood Data Resource Center (NBDRC) stated the position of her organization that a no-fault, confidential event reporting to a non-regulatory, non-accrediting organization would significantly increase error detection, reporting, and prevention, that such a program must either be mandatory or accompanied by sufficient financial incentives to achieve a high rate of participation, and that such a program should include both adverse events and near misses. She pointed out that the NBDRC currently serves the transfusion medicine community in many ways, and that it hopes to participate in the development and analysis of a reporting system for this community.

Dr. Linden commented that, in response to questions she received after her presentation on January 26th, that the cost of her reporting and analysis system was about $150 per facility covered per year, plus the facility cost of collecting the data. She noted that the cost of collecting the data itself should be considered essential to their business, and not an additional regulatory burden. Dr. Linden said that her agency was very flexible in its reporting formats, not only to minimize regulatory burden but also to facilitate compliance, and she emphasized that maximizing compliance required minimizing the cost of that compliance. Dr. Linden then mentioned the distinction between confidentiality and anonymity. She noted that the confidentiality of reports to her office was protected by state law, and that permitted her to maintain records at an organizational level that would permit measurement of improvement or other trends over time.

Dr. Ann Pozen of the National Association for Victims of Transfusion-Acquired AIDS requested that ethical as well as technical review of errors and accidents be conducted.

At the conclusion of the Public Comment period, Dr. Caplan noted that the inclement weather would require many of the Committee members to leave in the middle of the afternoon, so the members would have to consider their recommendations as expeditiously as possible. Dr. Caplan encouraged the Committee, when formulating its recommendations, to be mindful of the following points:

1. In transfusion medicine, substantial progress towards error management has already been made, so there is a foundation on which recommendations can be built;
2. Micromanagement is a dangerous thing.

3. The Committee is not required to solve liability issues before it determines what information should be collected. Instead, the establishment of data collection for error management systems might promote the resolution of liability issues.

Following a luncheon break and vigorous discussion, the Committee approved the following recommendations:

The experience of aviation and other industries supports the use in all blood establishments (i. e., both blood and plasma collection centers and facilities that provide transfusion services) of a confidential, non-punitive system for the management of errors and accidents not subject to regulatory requirements. (Proposed by Caplan, seconded by Hoots; approved unanimously.)

All blood establishments should have a quality assurance program. (Proposed by Guerra, seconded by Walsh; approved unanimously.)

Quality assurance programs in all blood establishments should capture, analyze, and respond to data on all deviations from established procedures, as well as errors and accidents, independent of whether affected blood units were distributed or caused adverse medical events. (Proposed by Secundy, seconded by Guerra; approved 13 to 1, with Piliavin opposing, AuBuchon abstaining, Haas and Lipton absent, and Caplan not voting except to break a tie.)

FDA should extend its current error and accident reporting requirements to apply to all blood establishments, including hospital transfusion services, rather than only to licensed blood establishments. (Proposed by Davey, seconded by Kuhn; approved 14 to 1, with AuBuchon opposing, Haas and Lipton absent, and Caplan not voting except to break a tie.)

In order to facilitate improved transfusion safety, for errors and accidents not subject to regulatory requirements, there should be established outside the regulatory framework an effective, confidential, non-punitive system for the accumulation, analysis, and dissemination of data from all blood establishments' quality assurance programs. (Proposed by Piliavin, seconded by Caplan; approved 11 to 3, with Allen, Kuhn, and Pahuja opposing, Busch, Haas, and Lipton absent, and Caplan not voting except to break a tie. There was disagreement among the Committee members whether the system proposed in this recommendation should be mandatory or not)

Industry and government should be encouraged to facilitate the evaluation and implementation of devices that promise to prevent misidentification of blood products and/or patients. (Proposed by AuBuchon, seconded by Walsh; passed unanimously.)

In the discussion that followed, Dr. Snyder asked if the Committee wished to consider recommending legislation to prevent discovery, and Mr. Allen asked if the Committee wished to consider further discussion of what information should be reported on a mandatory and what on a voluntary basis. Dr. Caplan suggested returning to these issues in April, and Dr. Nightingale suggested both April and

August as probable times for further discussion. Dr. Winkelstein appeared to reflect the sense of the Committee when he commented that

> ... the point of the last day and a half has been that there is something to be learned from near misses. So, that's going to influence my thinking on mandatory versus voluntary.

At that point, Mr. Walsh moved the meeting be adjourned, and Dr. AuBuchon seconded the motion. It passed unanimously at 3:20 PM.

This Summary of Meeting was approved by the Committee Chairman, Dr. Arthur Caplan, on February 7, 2000.

DATE: February 7, 2000

TO: Interested Parties

FROM: Stephen D. Nightingale, M. D., Executive Secretary
Advisory Committee on Blood Safety and Availability

SUBJECT: Resolutions Adopted at the January 26th and 27th, 2000 Meeting

1. The Committee directs its staff to create on the Committee's web site a list of key recommendations that the Committee has made, in a format that would permit the public to see what progress has been made in implementing each of these recommendations.

2. The experience of aviation and other industries supports the use in all blood establishments (i. e., both blood and plasma collection centers and facilities that provide transfusion services) of a confidential, non-punitive system for the management of errors and accidents not subject to regulatory requirements.

3. All blood establishments should have a quality assurance program.

4. Quality assurance programs in all blood establishments should capture, analyze, and respond to data on all deviations from established procedures, as well as errors and accidents, independent of whether affected blood units were distributed or caused adverse medical events.

5. FDA should extend its current error and accident reporting requirements to apply to all blood establishments, including hospital transfusion services, rather than only to licensed blood establishments.

6. In order to facilitate improved transfusion safety, for errors and accidents not subject to regulatory requirements, there should be established outside the regulatory framework an effective, confidential, non-punitive system for the accumulation, analysis, and dissemination of data from all blood establishments' quality assurance programs.

7. Industry and government should be encouraged to facilitate the evaluation and implementation of devices that promise to prevent misidentification of blood products and/or patients.